

X082606

Confidential

5-2

510(k) Summary

This summary is submitted in compliance with 21 CFR 807.92

NOV 10 2008

(a) (1) **Submitted by:** D3 Radiation Planning
5750 Centre Avenue, Suite 500
Pittsburgh, PA 15206

Trade name of the company: D3

Contact Persons: Nabil Adnani, Ph.D, DABR
412-365-0743

Date of preparation: 26 August – 2008

(2) **Trade name of device:** CDMS

Common name: Commissioning Data Management System

Classification name: (Accessory to) Radionuclide radiation therapy, §892.5750; X-ray radiation therapy system, §892.5900; and Medical charged-particle radiation therapy system, §892.5050.

(3) **Identification of predicate**

Marketed device: K010464 RadCalc V4.0.
K031975 IMSure.

(4) **Device Description:**

CDMS is a software program designed to record radiation beam data acquired during the commissioning, acceptance testing and calibration of a radiation therapy treatment device.

A CDMS session would look like this:

1. A new treatment machine is installed. The commissioning physicist enters its technical specification in CDMS.
2. A third party FDA approved water phantom is used to measure the physics characteristics of each beam generated by the machine.

3. Measured physics data is imported to CDMS.
4. Measured data in CDMS is compared to peer reviewed/published or manufacturer provided measured values.
5. Treatment plans generated by a radiation therapy treatment planning system imported to CDMS via DICOM RT.
6. Imported treatment fields parameters are used in conjunction with CDMS stored measured physics data to calculate dose and/or monitor units.
7. The difference between planned and CDMS calculations is used as a measure of the quality of the treatment plan (QA).

The above workflow is only given as an example to illustrate how the application is used. Other steps may be added to the workflow or may be left out, for example performing a query of the measured physics data based on beam type, energy and field geometry and saving calibration parameters for use on a monthly QA basis.

(5) Intended Use:

CDMS is a Microsoft Windows based software application designed to record and manage physics data acquired during acceptance testing, commissioning and calibration of radiation therapy treatment devices. In addition, CDMS uses the same physics data to allow users to perform MU calculations based on treatment field parameters that are either imported from the treatment planning system or entered manually. CDMS is also used to manage linac calibration using standard protocols.

(6) Technological Comparison:

The intended use of CDMS is the same as the predicate devices with a few additions that do not affect the safety and effectiveness of the device.

System Component	LifeLine Software, Inc. RadCalc, Model V.4.0	D3 Advanced Planning Service CDMS
K number	K010464	This filing
Application (use)	Utilized for the determination of monitor units or dose. Serves to validate those monitor units computed by the primary radiation therapy planning system. Primary means of calculating monitor units in situations where the physician does not order the use of a radiation therapy treatment plan.	Independent dose and monitor unit calculations for imported treatment plans from a radiation therapy treatment planning system. Performs monitor unit calculations for simple plan geometries based on a physician prescribed dose. It also records and manages measured beam data during acceptance testing, commissioning and calibration of radiation therapy devices.
Platform	Minimum Pentium II processor, MFS network enabled	Minimum Pentium II processor
Operating System	Any MS Windows	Windows 2000, XP, VISTA
MU Calculation Dose Algorithm	Khan (Classical)	Khan (Classical)
Algorithm - map verification	Single Source model	Not Available
Algorithm - IMRT dose Calculation	Single Source model, Clarkson scatter algorithm based on University of Chicago method	Not Available
Patient Geometry Specification	Two dimensional, graphical user interface based	Two dimensional, graphical user interface based
Machines supported	Commercially available Linear Accelerators with multi-modality energies and both photon and electron particles, including field blocking and linear wedge applicators for photon fluence modulation, and with 52, 80, 120 leaf Multi-leaf collimators	Commercially available Linear Accelerators with multi-modality energies and both photon and electron particles, including field blocking and linear wedge applicators for photon fluence modulation, and with 52, 80, 120 leaf Multi-leaf collimators
Calculation Point for IMRT QA	Fixed, Iso-centric	Not Available
Calculation point for MU calculations	Off axis and depth specified calculation points using measured physical data.	Off axis and depth specified calculation points using measured physical data.
Physics data	Measured, tabular database stored, multiple linear accelerators allowed.	Measured, tabular database stored, multiple linear accelerators allowed.
Import data	RTP link, DICOM RT for IMRT QA and MU Calculations	DICOM RT for independent MU Calculations Network location for measured data.
Calibration methods	Iso-centric or fixed Calibration Distance	Iso-centric or fixed Calibration Distance.
Export Data	RTP link, DICOM RT, paper documentation	Paper or electronic in the form of word, excel or PDF document.
User security	Two levels of user, password enabled	Three levels of users, password enabled

System Component	Standard Imaging, Inc. IMSure	D3 Advanced Planning Service CDMS
K number	K031975	This filing
Application (use)	Independent dose and fluence map verification software for Intensity Modulated Radiation Therapy based on Linear accelerator plans containing multi-leaf collimator leaf sequence data and fluence maps from primary IMRT treatment planning systems. Independent dose computation software for standard, simple geometry radiation therapy treatment planning and verification of monitor units based on Linear Accelerator parameters and physician prescribed dose information.	Independent dose and monitor unit calculations for imported treatment plans from a radiation therapy treatment planning system. Performs monitor unit calculations for simple plan geometries based on a physician prescribed dose. It also records and manages measured beam data during acceptance testing, commissioning and calibration of radiation therapy devices.
Platform	Minimum Pentium III processor, MFS network enabled	Minimum Pentium II processor
Operating System	Windows 2000, XP	Windows 2000, XP, VISTA
MU Calculation Dose Algorithm	Khan (Classical)	Khan (Classical)
Algorithm - map verification	Single Source model	Not Available
Algorithm - IMRT dose Calculation	Single Source model, Clarkson scatter algorithm based on University of Chicago method	Not Available
Patient Geometry Specification	Two dimensional, graphical user interface based	Two dimensional, graphical user interface based
Machines supported	Commercially available Linear Accelerators with multi-modality energies and both photon and electron particles, including field blocking and linear wedge applicators for photon fluence modulation, and with 52, 80, 120 leaf Multi-leaf collimators	Commercially available Linear Accelerators with multi-modality energies and photon and electron particles, including field blocking and linear wedge applicators for photon fluence modulation, and with 52,80 and 120 leaf Multi-leaf collimators
Calculation Point for IMRT QA	Off-Axis calculation points incorporating modeled head scatter information and measured fluence perturbations	Not Available
Calculation point for MU calculations	Off axis and depth specified calculation points using measured physical data.	Off axis and depth specified calculation points using measured physical data.
Physics data	Measured, tabular database stored, multiple linear accelerators allowed.	Measured, tabular database stored, multiple linear accelerators allowed.
Import data	RTP link, DICOM RT for IMRT QA and MU Calculations	DICOM RT for independent MU Calculations Network location for measured data.
Calibration methods	Iso-centric or fixed Calibration Distance	Iso-centric or fixed Calibration Distance.
Export Data	RTP link, DICOM RT, paper documentation	Paper or electronic in the form of word, excel or PDF document.
User security	Three levels of user, password enabled	Three levels of user, password enabled

CDMS differs from the predicate devices by allowing for the management linear accelerators calibration according to American Association of Physicists in Medicine (AAPM) Task Group 51. This feature is equivalent to using an excel sheet to perform the required calibration and save the necessary parameters for future use on monthly basis following AAPM Task Group 40 recommendations. It is therefore not seen to be a threat to patient safety and effectiveness. In fact, it is seen as an enhancement because it will allow for proper storage of calibration parameters as well as better management of calibration reports in format that is easily accessible to external auditors, state and federal regulators.

(7) Non-Clinical tests:

The non-clinical tests involved using CDMS to import measured physics data, to perform numerous monitor unit/dose calculations and to calibrate a linear accelerator according to TG-51. Side by side comparison tables are shown in the supporting Validation & Verification documentation

(8) Clinical tests:

Due to the fact that the system is a software application that is not directly involved with patient treatment delivery, no clinical tests were performed.

(9) Conclusion:

According to the intended use, technological characteristics and non-clinical testing, CDMS is substantially equivalent to IMSure and RadCalc, Model V4.0 (the predicate devices). The documentation presented in this submission supports the claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2008

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D3 Radiation Planning
5750 Centre Avenue, Suite 500
PITTSBURGH PA 15206

Re: K082606

Trade/Device Name: CDMS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: August 29, 2008
Received: September 8, 2008

Dear Dr. Adnani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082606

Device Name: CDMS

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CDMS is a Microsoft Windows based software application designed to record and manage physics data acquired during acceptance testing, commissioning and calibration of radiation therapy treatment devices. In addition, CDMS uses the same physics data to allow users to perform MU calculations based on treatment field parameters that are either imported from the treatment planning system or entered manually. CDMS is also used to manage linac calibration using standard protocols.

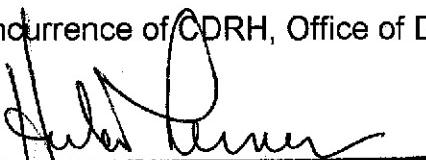
Prescription Use YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K082606

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